§ 522.1155 Imidocarb dipropionate sterile powder.

(a) *Specifications.* Imidocarb dipropionate powder is reconstituted with sterile water. Each milliliter of solution contains 100 milligrams of imidocarb base.

(b) *Sponsor.* No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* The drug is used in horses and zebras as follows:

(1) *Amount.* For *Babesia caballi* infections, use intramuscularly 2 milligrams of imidocarb base per kilogram of body weight, repeating dosage once after 24 hours. For *Babesia equi* infections, use 4 milligrams of imidocarb base per kilogram of body weight, repeating dosage four times at 72-hour intervals.

(2) *Indications for use.* For the treatment of babesiosis (piroplasmosis) caused by *Babesia caballi* and *Babesia equi.*

(3) *Limitations.* Administer intramuscularly in the neck region. Do not inject intravenously. Do not use for other equidae or for animals of other species. Do not use in horses less than 1 year old. Do not use for animals in near-term pregnancies. Imidocarb dipropionate is a cholinesterase inhibitor. Do not use this product simultaneously with or a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Do not use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Imidocarb dipropionate is sold only under permit issued by the Director of the National Program Planning Staff, Veterinary Services, APHIS, USDA, to licensed or full-time State, Federal, or military veterinarians.

[43 FR 40455, Sept. 12, 1978, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 522.1156 Imidocarb dipropionate solution.

(a) *Specifications.* Each milliliter of injectable solution contains 120 milligrams of imidocarb.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 6.6 milligrams imidocarb per kilogram (3 milligrams per pound) of body weight.

(ii) *Indications for use.* Treatment of clinical signs of babesiosis and/or demonstrated *Babesia* organisms in the blood.

(iii) *Limitations.* Use subcutaneously or intramuscularly. Not for intravenous use. Repeat the dose after 2 weeks for a total of two treatments. Imidocarb is a cholinesterase inhibitor. Do not use simultaneously with or a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[62 FR 66984, Dec. 23, 1997]

§ 522.1160 Insulin.

(a) *Specifications.* Each milliliter of porcine zinc insulin suspension contains 40 international units (IU) of insulin.

(b) *Sponsor.* See No. 057926 in § 510.600 of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* (i) Administer by subcutaneous injection. An initial once-daily dose, administered by subcutaneous injection concurrently with or right after a meal, is calculated as follows:

Body Weight	Initial Dose
<10 kg[1] (<22 lb[2])	1 IU/kg + 1 IU
10 to 11 kg (22 to 24 lb)	1 IU/kg + 2 IU
12 to 20 kg (25 to 44 lb)	1 IU/kg + 3 IU
>20 kg (>44 lb)	1 IU/kg + 4 IU

[1] kg means kilograms.
[2] lb means pounds.

(ii) Adjust the once-daily dose described in paragraph (c)(1)(i) of this section at appropriate intervals based on clinical signs, urinalysis results, and glucose curve/spot check values until adequate glycemic control has been attained. Twice-daily therapy should be initiated if the duration of insulin action is determined to be inadequate. If twice-daily treatment is initiated, the two doses should be 25 percent less than the once daily dose required to attain an acceptable nadir.

(2) *Indications for use.* For the reduction of hyperglycemia and hyperglycemia-associated clinical signs in dogs with diabetes mellitus.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 25827, May 10, 2004]

§ 522.1182 Iron dextran complex injection.

(a)(1) *Specifications.* Each milliliter of sterile solution contains ferric hydroxide dextran complex equivalent to 100 milligrams of elemental iron. It contains 0.5 percent phenol as a preservative.

(2) [Reserved]

(3)(i) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(ii) *Conditions of use.* It is used in baby pigs as follows:

(*a*) For the prevention of anemia due to iron deficiency, administer an initial intramuscular injection of 100 milligrams of elemental iron to each animal at 2 to 4 days of age. Dosage may be repeated in 14 to 21 days.

(*b*) For the treatment of anemia due to iron deficiency, administer and intramuscular injection of 200 milligrams of elemental iron.

(4)(i) *Sponsor.* See Nos. 000061 and 062408 in § 510.600(c) of this chapter.

(ii) *Conditions of use.* It is used in baby pigs as follows:

(*a*) For the prevention of iron deficiency anemia, administer intramuscularly an amount of drug containing 100 to 150 milligrams of elemental iron to animals from 1 to 3 days of age.

(*b*) For the treatment of iron deficiency anemia, administer intramuscularly an amount of drug containing 100 to 200 milligrams of elemental iron per animal. Dosage may be repeated in 10 days to 2 weeks.

(b)(1) *Specifications.* Each milliliter of sterile solution contains ferric hydroxide in complex with dextran equivalent to 200 milligrams of elemental iron. It contains 0.5 percent phenol as a preservative.

(2)(i) *Sponsor.* See Nos. 000010 and 059130 in § 510.600(c) of this chapter.

(ii) *Conditions of use.* It is used in baby pigs as follows:

(*a*) For prevention of baby pig anemia due to iron deficiency, intramuscularly inject 200 milligrams of elemental iron (1 milliliter) at 1 to 3 days of age.

(*b*) For treatment of baby pig anemia due to iron deficiency, intramuscularly inject 200 milligrams of elemental iron at the first sign of anemia.

[49 FR 38938, Oct. 2, 1984, as amended 52 FR 7832, Mar. 13, 1987; 53 FR 40727, Oct. 18, 1988; 54 FR 41442, Oct. 10, 1989; 61 FR 18672, Apr. 29, 1996; 62 FR 35076, June 30, 1997; 63 FR 53578, Oct. 6, 1998]

§ 522.1183 Iron hydrogenated dextran injection.

(a) *Specifications.* Each milliliter contains 100 milligrams of elemental iron stabilized with a low molecular weight hydrogenated dextran and 0.5 percent phenol as a preservative.

(b)–(c) [Reserved]

(d)(1) *Sponsor.* See No. 000003 in § 510.600(c) of this chapter.

(2) *Conditions of use.* It is used in baby pigs as follows:

(i) For the prevention of anemia due to iron deficiency, administer by intramuscular or subcutaneous injection of 100 milligrams of elemental iron to each animal at 2 to 4 days of age.

(ii) For the treatment of anemia due to iron deficiency, administer by intramuscular or subcutaneous injection of 100 milligrams of elemental iron in baby pigs up to 4 weeks of age.

(e)(1) *Sponsors.* See Nos. 000010, 058005, and 059130 in § 510.600(c) of this chapter.

(2) *Conditions of use.* It is used in baby pigs as follows:

(i) For the prevention of iron deficiency anemia, administer intramuscularly 100 milligrams at 2 to 4 days of age.

(ii) For the treatment of iron deficiency anemia, administer intramuscularly 100 milligrams. Treatment may be repeated in 10 days.

[42 FR 53955, Oct. 4, 1977, as amended at 46 FR 39128, July 31, 1981; 50 FR 23298, June 3, 1985; 52 FR 18691, May 19, 1987; 52 FR 36023, Sept. 25, 1987; 53 FR 40728 and 40729, Oct. 18, 1988; 55 FR 8462, Mar. 8, 1990; 55 FR 33670, Aug. 17, 1990; 62 FR 35076, June 30, 1997; 63 FR 44384, Aug. 19, 1998; 65 FR 45877, July 26, 2000; 66 FR 22117, May 3, 2001; 69 FR 47361, Aug. 5, 2004]